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14. ABSTRACT The project is currently undergoing review by the human subjects review at the Walter Reed Army Medical Center and the Army (USAMRMC ORP HRPO). The materials were submitted to the Walter Reed committee in June, 2009, and we have responded to their comments. Dr. Stephenson is assisting us in preparing documents of the Army review committees. The Westat IRB has reviewed and approved the activities of the Westat team. In the meantime, the research team has had several opportunities to present the project in a variety of settings and have been provided opportunities to further develop the theory behind the concept of using service dogs to reduce the symptoms of PTSD among returning soldiers with severe cases of the disability.					
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INTRODUCTION

The proposed project will study the effectiveness of service dogs in the reduction of PTSD symptoms among soldiers returning to the Walter Reed Army Medical Center (WRAMC) from Iraq and Afghanistan. The Psychiatric Service Dog Society (PSDS) has been developing the concept of using service dogs with a variety of mental health disabilities, including PTSD for the past 13 years. In a 2005 survey of Psychiatric Service Dog (PSD) handlers, 82% of the respondents with PTSD who are using a PSD reported a decline in symptom manifestation. That finding among others and the strong interest of veterans and returning soldiers, the PSD launched a listserv community for veterans of all wars who are interested in using a service dog to help reduce refractory symptoms of PTSD. The community grows on a continuing basis and after 1 year has grown beyond 150 subscribers who are actually using service dogs.

The funded research project will be the first direct test of the effectiveness of service dogs for returning warriors who are suffering from PTSD. It is a “seedling” study that will engage only 20 soldiers. They will be randomly assigned to two groups one receiving the service dog and training to handle it and the second will not receive such support until the end of the project. The measures will include behavioral assessments of general mental health and PTSD symptom manifestations as well as the biological markers that are associated with anxiety, stress and depression. The parallel measures will strengthen the study and add power to the analyses. Once the data collection is complete, and if the findings are positive, there will be a need for a larger study examining the effects of PSDs on PTSD. The study is being administered and data collected by an independent party, the lead agency, Westat.

HUMAN SUBJECTS REVIEW ACTIVITIES

Dr. Bouterie, with extensive support from Drs. Love and Esnayra, has worked with the WRAMC human subjects review committee to ensure an efficient review of our protocol. She submitted the completed document on June 1, 2009 and received comments and questions in August, 2009, to which we responded. We have made subsequent changes in the document and have resubmitted the document. We look forward to the review hearing on November 16 to complete the process.

Dr. Stephenson, who is the TATRIC staff member who is assisting us in preparing

the USAMRMC ORP HRPO review has provided feedback on our protocol in preparation for the second level of review.

PRESENTATIONS AND PUBLICITY

In the meantime, the research team has had the opportunity to present the research project in several venues. The ensuing discussions have helped strengthen the development of the theoretical understanding of the way service dogs assist returning soldiers with PTSD. The veterans' listserve has provided extensive insight in ways that the dog assists persons with PTSD (See Appendix). It appears that the service dog provides assistance that is understood by the dog's handler. That is, the assistance is a construction in the mind of the handler, based on the dog's responses to the handler's behavior and understanding of his/her disability. This calls for a clear collaboration among the trainer, the treatment provider, the client and an expert on service dog functions.

Some design issues were raised in the February 2009 CRMRP meeting that addressed the small number of subjects. Because of the required costs of establishing the intervention, the budget allowed only 20 subjects. Some of the CDRMP leaders suggested that the study be doubled in size to allow for a larger sample size and increase the power. We are very interested in such an opportunity and are looking forward to the possibility. However, we believe that the design will allow us to develop an effect size that can be used in future larger studies. The matching component in the randomization procedure, multiple data points and multi-method measurements will all contribute to a more stable variance and enhance the likelihood of a reasonable effect size.

Presentations:

1. September 2010. Presented at a "Congressional Roundtable" at the invitation of Congressman Filner. The presentations focused on innovative ways to address PTSD among our returning soldiers. The concept was well received and Congressman Filner expressed support for the project. Drs. Love and Esnayra responded to questions from the Congressman and the Roundtable participants.

Publicity:

1. Drs. Love and Esnayra have been interviewed by a Time magazine reporter who is very interested in the project at Walter Reed and some of the legal

and political issues that have arisen in the course of advancing the use of service dogs for soldiers suffering from PTSD. We have not been apprised of any publication date.

2. In December, 2009, the St. Louis Post-Dispatch featured several soldiers with PTSD who use service dogs. The article also discussed the Walter Reed Study that is still in planning.
3. Bark Magazine published a similar article on the way dogs are serving soldiers with PTSD. They also featured the Walter Reed Study.

STAFFING ADJUSTMENTS

The key project staff have not changed; Drs. Bouterie and Soumoff (WRAMC PI), Dr. Love (Project PI) and Dr. Esnayra (Project Co-PI) are all very much involved. The training component has not changed. The Washington Humane Society, a group who has a kennel facility across the street from the Walter Reed facility and who already has a relationship with the WRAMC in their “Dog Tag” program will provide the training.

APPENDIX 1

Service Dog Functions for Persons With PTSD

PSD Assistance for persons with PTSD

Symptom(s): assistive behaviors	assistance classification
reclusiveness: canine accompanies veteran outside the home	physical task
night terrors: dog wakes veteran (optional: turn on light)	physical task
startle reaction: canine-defined personal space perimeter	physical task
forgetfulness: canine medication reminder	physical task
dissociative fugue: 'take me home' command	physical task
hypervigilance: search a room for the presence of humans	physical task
neurochemical imbalance: Team walks to stimulate endorphin production	physical task
dissociative flashback: tactile stimulation mediates sensory re-integration and orientation to time/place	physical task
alert to presence of others (i.e., 'pop a corner' or 'watch my back')	work--leveraging a dog's natural senses
dissociative spell: canine interrupts	work--mind/body
emotional regulation: canine as therapeutic distraction	work--mind/body
sensory overload:	work--mind/body

canine as alternate focus	
social withdrawal: canine-facilitated interpersonal interaction	work--community integration
canine alert to emotional escalation	work-- leveraging a dog's natural senses (CBT)
hypervigilance: canine environmental threat assessment	work--leveraging a dog's natural senses (CBT)
hallucinations: canine-facilitated reality testing	work--leveraging a dog's natural senses (CBT)
suicidal ideation: 'suicide prevention dog'	work—(CBT)